

REMARKS/ARGUMENTS

Support for each amended claim is found, for example, at the originally filed claims and throughout the originally filed specification.

No new matter is added.

Applicants have perfected priority by filing, along with this paper, a certified English language translation of parent Japanese Patent Application No. 2004-48593, filed February 24, 2004.

The 35 U.S.C. § 101 rejection of Claims 5 and 10 is traversed. Present Claim 5 is drawn to a method for predicting the postoperative prognosis, in node-negative (n0) breast cancer with no metastasis to a lymph node in operation by measuring expression of a galectin 1 gene. Because, in the method of Claim 5, expression of a galectin 1 gene, and not the galectin 1 gene itself, is claimed, the “hand of man” concern (see page 6 of the Official Action) is obviated. Accordingly, Applicants submit Claim 5, and Claim 10 that depends from Claim 5, are drawn to statutory subject matter. Withdrawal of the rejection is requested.

The indefiniteness rejection of Claims 5, 10-12 and 17-19 is traversed. Claims 5, 10-12 and 17-19, as amended, do not contain accession numbers (see page 6 of the Official Action). Additionally, the parentheses around “node negative” are removed in amended Claim 5 (see page 6 of the Official Action). Further, the term “a reagent using as a marker the gene and/or probe” is amended to recite “a reagent comprising as a marker galectin 1 gene and/or a probe specific thereto” (see page 7 of the Official Action). Accordingly, Applicants submit the bases for making the indefiniteness rejection are mooted. Withdrawal of the obviousness rejection is requested.

The anticipation rejection of Claims 5 and 10-12 as being unpatentable in view of Nagahata is traversed. The present application claims priority to International Application No. PCT/JP04/12455, filed on August 24, 2004, and to Japanese Patent Application No. JP

2004-048593, filed on February 24, 2004. Nagahata published March 15, 2004. Thus, based on the effective filing date of the present application, August 24, 2004, Nagahata is not prior art under 35 U.S.C. § 102(b). As described, *supra*, Applicants perfected priority by filing, along with this paper, a certified English language translation of Japanese Patent Application No. JP 2004-048593 ('593), filed on February 24, 2004. Because the February 24, 2004 filing date of the '593 parent application predates the March 15, 2004 publication date of Nagahata, Applicants request removal of Nagahata as a reference and withdrawal of the anticipation rejection.

The anticipation rejection of Claims 5 and 10-12 as being unpatentable in view of Mackay is traversed. As described, *supra*, present Claim 5 is drawn to a method for predicting the postoperative prognosis, in node-negative (n0) breast cancer with no metastasis to a lymph node in operation by measuring expression of a galectin 1 gene. Thus, in the method of present Claim 5, there is a correlation between expression of galectin 1 and breast cancer and between galectin 1 and postoperative prognosis of breast cancer. Mackay does not describe or suggest at least these features of present Claims 5 and 10-12. For example, in Mackay, a cell appears to be transfected with ERBB2 cDNA derived from a breast cancer cell line, BT474, the cell itself is a normal mammary luminal epithelial cell line (HB4a) which is not a cancer cell (*see* page 2685, right column, of Mackay). Further, Mackay describes "[t]hese cells do not exhibit amplification at 17q12-21, and thereby provide an opportunity to examine ERBB2-related signaling independent of the effects of other related coamplified genes" (*see* page 2680, right column, of Mackay). Applicants submit this description, *supra*, indicates that Mackay intends to simplify the system to observe pure effects of ERBB2-related signaling by excluding the possible influence of the "coamplified genes" by using the normal mammary luminal epithelial cell line. Thus, Mackay does not describe or suggest data

which reflect the conditions of breast cancer; indeed, such conditions are excluded on purpose. In summary, because Mackay does not describe or suggest that there is a correlation between expression of galectin 1 and breast cancer and between galectin-1 and postoperative prognosis of breast cancer as found, for example, in present Claim 5, Mackay cannot anticipate or render obvious present Claims 5, and 10-12. Withdrawal of the obviousness rejection is requested.

The anticipation rejection of Claims 5 and 10 as being unpatentable in view of Soares is traversed. As described, *supra*, in the method of present Claim 5, there is a correlation between expression of galectin 1 and breast cancer and between galectin-1 and postoperative prognosis of breast cancer. Soares does not describe or suggest at least these features of Claim 5 (and Claim 10 that depends from Claim 5). Withdrawal of the obviousness rejection is requested.

The anticipation rejection of Claims 5 and 10 as being unpatentable in view of Couraud is traversed. As described, *supra*, in the method of present Claim 5, there is a correlation between expression of galectin 1 and breast cancer and between galectin 1 and postoperative prognosis of breast cancer. Couraud does not describe or suggest at least these features of Claim 5 (and Claim 10 that depends from Claim 5). Withdrawal of the obviousness rejection is requested.

The anticipation rejection of Claims 5, 10-12 and 17-19 as being unpatentable in view of Kurn is traversed. As described, *supra*, in the method of present Claim 5, there is a correlation between expression of galectin 1 and breast cancer and between galectin 1 and postoperative prognosis of breast cancer. Kurn does not describe or suggest at least these features of Claim 5 (and the claims depending therefrom). Withdrawal of the obviousness rejection is requested.

Applicants request rejoinder of the withdrawn claims under M.P.E.P. § 821.04.

Applicants submit the present application is now in condition for allowance. Early notification to this effect is earnestly solicited.

Respectfully submitted,

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Richard L. Treanor

A handwritten signature in black ink, appearing to be 'CJ Andres', written over a horizontal line.

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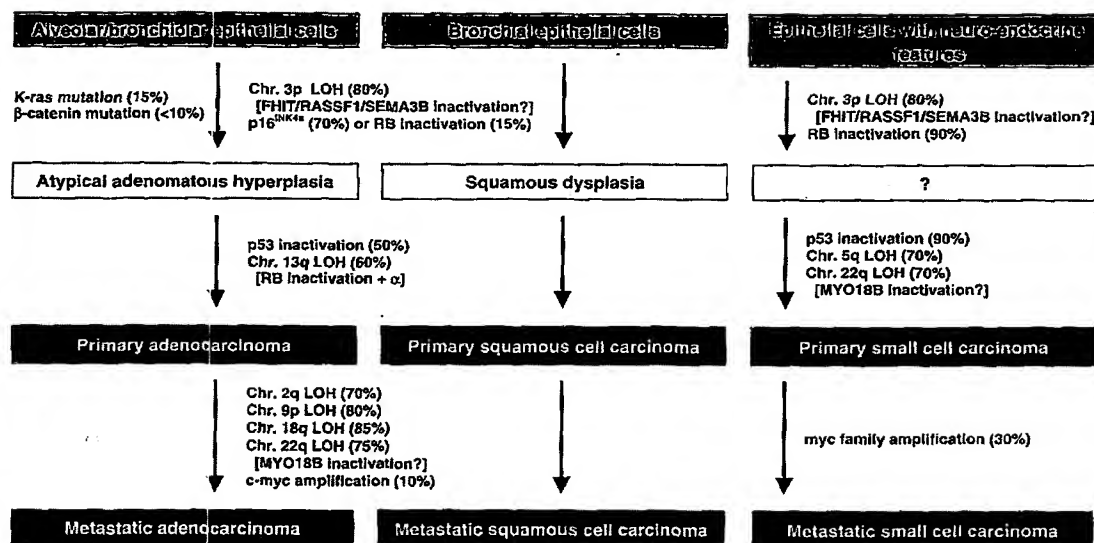
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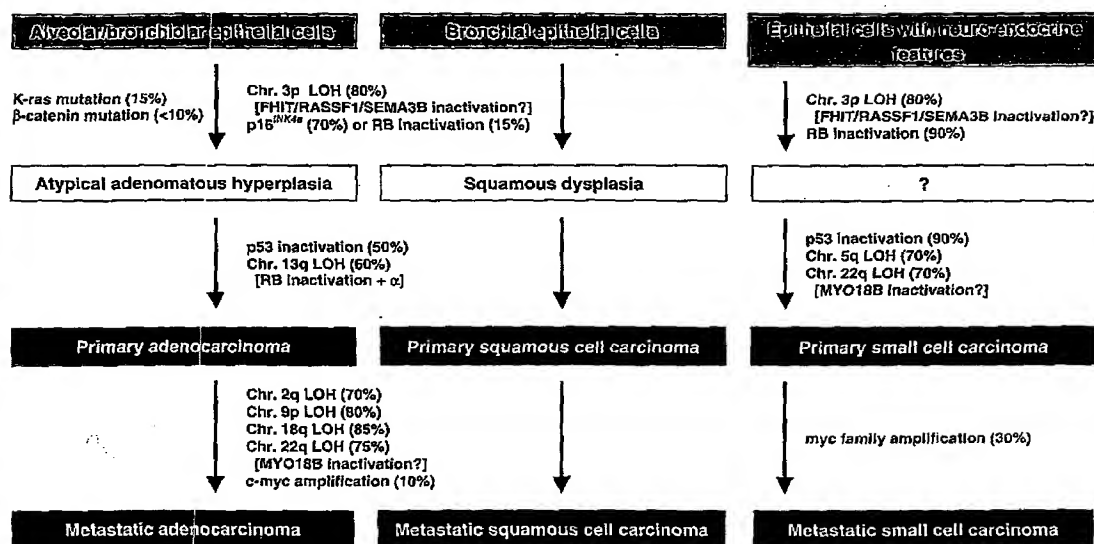
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